§431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The erythromycin estolate used in making the batch for potency, pH, moisture, crystallinity, and identity.

(*b*) The batch for potency, moisture, and pH.

(ii) Samples required:

(*a*) The erythromycin estolate used in making the batch: 10 packages, each containing not less than 300 milligrams.

(*b*) The batch: A minimum of 5 immediate containers.

(b) *Tests and methods of assay*—(1) *Potency*. Proceed as directed in §436.105 of this chapter, preparing the sample for assay as follows: Reconstitute the sample as directed in the labeling. Withdraw an accurately measured representative volume of the reconstituted suspension and add sufficient methyl alcohol to give a concentration of 2.5 milligrams of erythromycin base per milliliter (estimated). Dilute this entire mixture with sufficient 0.1*M* potassium phosphate buffer, pH 8 (solution 3), to give a concentration of 1.0 milligram of erythromycin base per milliliter (estimated). Hydrolyze in a 60° C. constant temperature water bath for 2 hours or at room temperature for 16 to 18 hours. Further dilute with solution 3 to the reference concentration of 1.0 microgram of erythromycin base per milliliter (estimated).

(2) *Moisture.* Proceed as directed in §436.201 of this chapter.

(3) *pH.* Proceed as directed in §436.202(b) of this chapter, using the suspension prepared as directed in the labeling.

[39 FR 19149, May 30, 1974, as amended at 50 FR 19921, May 13, 1985]

§452.115f Erythromycin estolate chewable tablets.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity*. Erythromycin estolate chewable tablets are tablets composed of erythromycin estolate and suitable and harmless diluents, binders, buffers, colorings, and flavorings. Each tablet contains erythromycin estolate equivalent to either 125 or 250 milligrams of erythromycin. Its potency is satisfactory if it is not less than 90 percent and not more than 115 percent of the number of milligrams of erythromycin that it is represented to contain. The moisture content is not more than 4 percent. The erythromycin estolate used in making the batch conforms to the standards prescribed by §452.15(a)(1).

(2) *Labeling.* It shall be labeled in accordance with §432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to the requirements of §431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The erythromycin estolate used in making the batch for potency, moisture, pH, crystallinity, and identity.

(*b*) The batch for potency and moisture.

(ii) Samples required:

(*a*) The erythromycin estolate used in making the batch: 10 packages, each consisting of not less than 300 milligrams.

(*b*) The batch: A minimum of 30 tablets.

(b) *Tests and methods of assay*—(1) *Potency*. Proceed as directed in §436.105 of this chapter, preparing the sample for assay as follows: Blend a representative number of tablets in a high-speed glass blender for 2 to 3 minutes in 200 milliliters of methyl alcohol. Add 300 milliliters of 0.1*M* potassium phosphate buffer, pH 8.0 (solution 3), and blend again for 2 to 3 minutes. Hydrolyze this solution in a 60° C. constant temperature water bath for 2 hours or at room temperature for 16 to 18 hours. Further dilute with solution 3 to the reference concentration of 1.0 microgram of erythromycin base per milliliter (estimated).

(2) *Moisture.* Proceed as directed in §436.201 of this chapter.

[39 FR 19149, May 30, 1974, as amended at 50 FR 19921, May 13, 1985]

§452.115g Erythromycin estolate and sulfisoxazole acetyl oral suspension.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity*. Erythromycin estolate and sulfisoxazole acetyl oral suspension is erythromycin estolate and sulfisoxazole acetyl with suitable and harmless buffer substances, preservatives, solvents, stabilizers, emulsifiers, dispersing agents, colorings, and

flavorings. Each milliliter contains erythromycin estolate equivalent to 25 milligrams of erythromycin and 120 milligrams of sulfisoxazole. Its erythromycin content is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of erythromycin that it is represented to contain. Its sulfisoxazole acetyl content is satisfactory if it is not less than 90 percent and not more than 115 percent of the number of milligrams of sulfisoxazole that it is represented to contain. Its pH is not less than 3.5 and not more than 6.5. The erythromycin estolate used conforms to the standards prescribed by §452.15(a)(1). The sulfisoxazole acetyl used conforms to the standards prescribed by the U.S.P. XXII.

(2) *Labeling.* It shall be labeled in accordance with the requirements of §432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of §431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(A) The erythromycin estolate used in making the batch for potency, moisture, pH, crystallinity, and identity.

(B) The sulfisoxazole acetyl used in making the batch for all U.S.P. XXII specifications.

(C) The batch for erythromycin content, sulfisoxazole content, and pH.

(ii) Samples, if required by the Center for Drug Evaluation and Research:

(A) The erythromycin estolate used in making the batch: 10 packages, each containing not less than 500 milligrams.

(B) The batch: a minimum of 15 immediate containers.

(b) *Tests and methods of assay*—(1) *Erythromycin content.* Proceed as directed in §436.105 of this chapter, preparing the sample for assay as follows: Remove an accurately measured representative volume of the suspension and dilute with sufficient methyl alcohol to give a concentration of 2.5 milligrams per milliliter (estimated). Dilute the entire mixture with sufficient 0.1*M* potassium phosphate buffer, pH 8.0 (solution 3), to give a concentration of 1.0 milligram of erythromycin base per milliliter (estimated). Hydrolyze in a 60 °C constant temperature water bath for 2 hours or at room temperature for 16 to 18 hours. Further dilute with solution 3 to the reference concentration of 1.0 microgram of erythromycin base per milliliter (estimated).

(2) *Sulfisoxazole content.* Proceed as directed in §436.328 of this chapter.

(3) *pH.* Proceed as directed in §436.202 of this chapter, using the drug as it is prepared for dispensing.

[55 FR 280, Jan. 4, 1990]

§ 452.125 Erythromycin ethylsuccinate oral dosage forms.

§ 452.125a Erythromycin ethylsuccinate chewable tablets.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Erythromycin ethylsuccinate chewable tablets are composed of erythromycin ethylsuccinate and suitable and harmless diluents, binders, buffers, colorings, and flavorings. Each tablet contains erythromycin ethylsuccinate equivalent to 200 milligrams of erythromycin. Its potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of erythromycin that it is represented to contain. The moisture content is not more than 5 percent. The erythromycin ethylsuccinate used conforms to the standards prescribed by §452.25(a)(1).

(2) *Labeling.* In addition to the labeling requirements prescribed by §432.5 of this chapter, this drug shall be labeled ''erythromycin ethylsuccinate tablets''.

(3) *Requests for certification; samples.* In addition to the requirements of §431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The erythromycin ethylsuccinate used in making the batch for potency, moisture, pH, residue on ignition, identity, and crystallinity.

(*b*) The batch for potency and moisture.

(ii) Samples required:

(*a*) The erythromycin ethylsuccinate used in making the batch: 10 packages, each consisting of 500 milligrams.

(*b*) The batch: A minimum of 36 tablets.